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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/269,999 06/28/99 SMITH

R S1011/20102

EXAMINER

HM12/0925

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ART UNIT

PAPER NUMBER

1615

12

DATE MAILED:

09/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/269,999

Applicant(s)

SMITH ET AL.

Examiner

Todd D Ware

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) ____ is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: .

DETAILED ACTION

Receipt of amendment file 7-9-01 is acknowledged. Claims 11-19 are canceled and claims 20 and 37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 9.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 21-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Recitation of "undersinter" is indefinite as this does not appear to be a term of the art and the specification does not appear to define what is meant by undersintering. Furthermore, sintering is defined as "The agglomeration of metal or earthy powders at temperatures below the melting point" Hawley's Condensed Chemical Dictionary (1971) and the instant claim 21 states in the preamble "A method of making a porous article composed of bonded particles..." Emphasis is placed upon bonded particles. Thus, it appears that since the articles are composed of bonded (agglomerated) particles formed by firing the polymer foamed structure, the article is sintered. Also, it appears that undersintering is a separate step from firing the article. Is this the case, or is undersintering what occurs after firing the article. Clarification is requested. For

purposes of examination, undersintering is interpreted as occurring upon firing the article at 1250° C or 1350° C.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 21-29, 31-33 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Sambrook et al (WO 93/04013; hereafter '013).

'013 discloses all the limitations of the instant claims. See the abstract and page 7, line 4 - page 8, line 13 and examples. The pore sizes are disclosed as being dependant on the filter (page 7, last two lines). Filter sizes are then discloses in the examples as being 10-16 microns. Also, Example VIII discloses that the mean pore diameter is 24 microns. Controlling the polymerization rate is disclosed at the bottom of page 11).

Response to Arguments

5. Applicant's arguments filed 7-9-01 have been fully considered but they are not persuasive. Applicants argue that the actual pore size of the end product is not mentioned and while '013 discloses that the final pore size of the foam may be dependent on the pore size of the filter, the final pore size can not be determined from this alone as the final pore size is also dependent upon the degree of expansion and

speed of stirring when introducing gas bubbles affects the pore size of the article. In response, it is submitted that '013 discloses the final pore size in Example XIII and that this pore size is within the instant range.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 21- 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sambrook et al (WO 93/04013; hereafter '013).

'013 teaches all the limitations of the instant claims. '013 does not specify pore sizes greater than 150 microns. '013 does teach adjustment of the pore size through choice of filter, drying under reduced pressure, which causes the foam to expand, or adjusting the speed of stirring when introducing the gas bubbles. Accordingly, adjustment of the pore size would be obvious to one skilled in the art at the time of the invention according to the nature of the intended article (i.e. impregnation of the pores with agents). Firing the solid article at 1350° C is disclosed in '013 and results in a final pore size within the instant range. Thus, firing the solid article at 1250° C does not appear to be critical as the same final pore size appears to be achieved. Controlling the polymerization rate is disclosed at the bottom of page 11).

Art Unit: 1615

8. Claims 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sambrook et al (WO 93/04013; hereafter '013) in view of Takagi et al (US 4,654,314; hereafter '314) or vice versa.

'013 is relied upon for all that it teaches as stated previously. '013 does not specifically state including the subsequent step of growing bone cells in the porous ceramic product. '013 does state that the products are useful for artificial parts for the body.

'314 is relied upon for teaching that artificial parts comprising growth of bone cells in ceramic products is known. '314 also teaches that the pores of the ceramic product should be between 1 and 600 μm to promote induction of "new-born bone" and turnover of a bone while keeping a good compatibility with a living body.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to incorporate bone cells into the invention of '013 with the motivation of using the ceramic products as artificial parts comprising growth of bone cells and the expectation that the products would be useful for inducing new-born bone, controlling resorption of bone with age, and remedying bone defects.

Also, it would have been obvious to one skilled in the art at the time of the invention to incorporate the invention of '013 into the teachings of '314 as the method of making the ceramic products and the resulting products of '013 may be made more quickly, with better mechanical strength and handling and machining characteristics.

9. Claims 21-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sambrook et al (WO 93/04013; hereafter '013) in combination with Hawley's Condensed Chemical Dictionary (1971) and further in combination with Takagi et al (US 4,654,314; hereafter '314).

'013 and '314 are relied upon for all that they teach as stated previously.

Hawley's Condensed Chemical Dictionary (1971) is relied upon for teaching that the energy required for reduction in particle size of a solid is directly proportional to the increase in surface area (Rittinger's law). In other words, the less energy results in less surface area and bigger particle size which would create larger pores in the same fashion as the space between large marbles in a jar is greater than the space between grains of sand in the same jar.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to decrease the heat (energy) of '013 to achieve larger pore sizes based upon '314, which teaches that the pores of the ceramic product should be between 1 and 600 μm to promote induction of "new-born bone" and turnover of a bone while keeping a good compatibility with a living body and Hawley's which teaches that less energy results in less surface area and bigger particle size which would create larger pores.

Response to Arguments

10. Applicant's arguments filed 7-9-01 have been fully considered but they are not persuasive. Applicants argue that the actual pore size of the end product is not mentioned in either '013 or '314 and while '013 discloses that the final pore size of the

Art Unit: 1615

foam may be dependent on the pore size of the filter, the final pore size can not be determined from this alone as the final pore size is also dependent upon the degree of expansion and speed of stirring when introducing gas bubbles affects the pore size of the article. In response, it is submitted that '013 discloses the final pore size in Example XIII and that this pore size is within the instant range. '314 teaches the final pore size (capillary voids) as between 1 and 600 microns.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1615

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on 7:30 AM - 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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September 22, 2001